Message

From: McClure, Peter [mcclure@srcinc.com]

Sent: 6/6/2014 3:29:49 PM

To: Pratt, Margaret [pratt.margaret@epa.gov]; Chiu, Weihsueh [Chiu.Weihsueh@epa.gov]; Hogan, Karen

[Hogan.Karen@epa.gov]; Rice, Glenn [rice.glenn@epa.gov]

CC: Carlson-Lynch, Heather [hclynch@srcinc.com]; Melia, Julie [jmelia@srcinc.com]

Subject: PAH RPF IRIS project: More comments and questions on analysis of "Zero-Incidence" data sets

Margaret -

Thanks for sending Karen's additional instructions. From them, it appears that we made three erroneous assumptions:

Ex. 5 Deliberative Process (DP)

If a study has or will have a calculated RPF (based on BMDs), should that value be used in place of the cRPF?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Peter

Peter McClure, PhD, DABT Senior Toxicologist SRC, Inc. 7502 Round Pond Road North Syracuse, New York 13212 315 452 8420 (T) 315 452 8440 (F)

From: Pratt, Margaret [mailto:pratt.margaret@epa.gov]

Sent: Tuesday, June 03, 2014 6:26 PM

To: McClure, Peter; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn

Cc: Carlson-Lynch, Heather; Melia, Julie

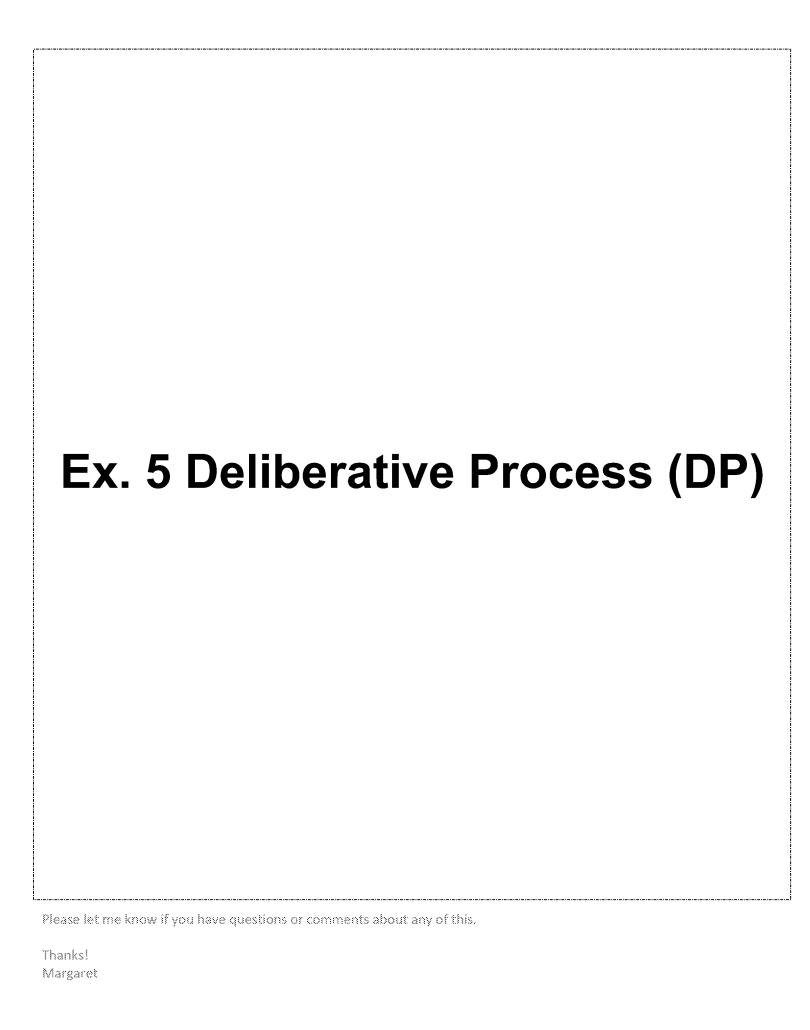
Subject: RE: PAH RPF IRIS project: Analysis of "Zero-Incidence" data sets

Hi Peter,

Karen hasn't had an opportunity to thoroughly look over the email you sent earlier today, but she did bring to my attention the fact that I neglected to forward some of the information that was supposed to go to SRC. I apologize for the confusion.

The following are examples and discussion that should also have been sent to you with what you received previously (below). I've highlighted where SRC's response today differed from Karen's examples in the previously omitted information:

Ex. 5 Deliberative Process (DP)



Once again, my apologies for the confusion. I look forward to receiving your comments.
Margaret
From: McClure, Peter [mailto:mcclure@srcinc.com] Sent: Tuesday, June 03, 2014 2:53 PM To: Pratt, Margaret; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn Cc: Carlson-Lynch, Heather; Melia, Julie Subject: PAH RPF IRIS project: Analysis of "Zero-Incidence" data sets
Margaret –
We have applied the methodology outlined in your email to determine which studies will be considered to be null (i.e., not useful for RPF derivation), based on inadequate dose level to elicit a response. In applying the methodology, we made certain assumptions as outlined below.
Ex 5 Dolihorativo Process (DD)
Ex. 5 Deliberative Process (DP)
<u></u>

Ex. 5 Deliberative Process (DP)

Please let us know if these thoughts and results are in line with your technical directive. Thank you,

Peter

Peter McClure, PhD, DABT Senior Toxicologist SRC, Inc. 7502 Round Pond Road North Syracuse, New York 13212 315 452 8420 (T) 315 452 8440 (F)

From: Pratt, Margaret [mailto:pratt.margaret@epa.gov]

Sent: Monday, June 02, 2014 9:52 AM

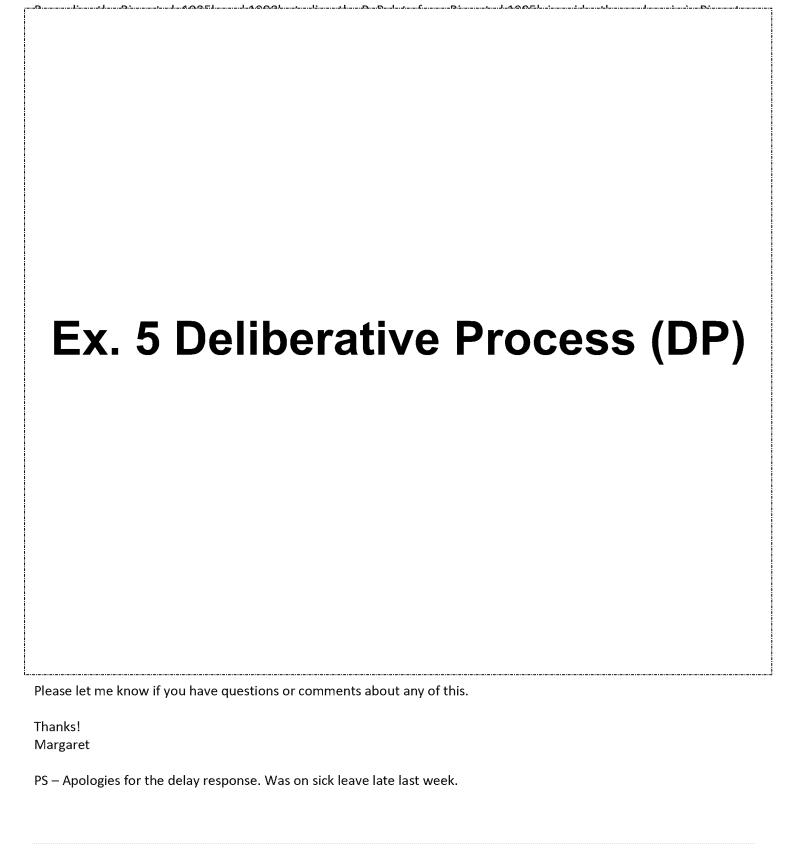
To: McClure, Peter; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn

Cc: Carlson-Lynch, Heather; Melia, Julie

Subject: RE: Call notes May 27 and revised RPF status spreadsheet

Hi Peter,

Thanks for the notes. After an initial look, I saw nothing that needed to be changed. I will let you know if someone else did.



 $\textbf{From:} \ \mathsf{McClure}, \mathsf{Peter} \ [\underline{\mathsf{mailto:mcclure@srcinc.com}}]$

Sent: Wednesday, May 28, 2014 11:57 AM

To: Pratt, Margaret; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn

Cc: Carlson-Lynch, Heather; Melia, Julie

Subject: Call notes May 27 and revised RPF status spreadsheet

Margaret et al.

Attached are notes for the May 27 call and a revised tracking spreadsheet in accordance with our discussions yesterday. The revised spreadsheet identifies additional "time-course" data sets that will need Bayesian analysis. We look forward to receiving information on blue and orange highlighted studies in the current version.

Let us know if you have questions or comments.

Thank you, Peter

Peter McClure, PhD, DABT Senior Toxicologist SRC, Inc. 7502 Round Pond Road North Syracuse, New York 13212 315 452 8420 (T) 315 452 8440 (F)